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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

March 30, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
CIN-WL-99-202

Kevin Benoit, President
Stille Beta Inc.
530 S. Main St., Bldg. #17
Akron, Ohio 44311

Dear Mr. Benoit:

We are writing to you because during an inspection of your firm located at the above address by the Food and Drug Administration (FDA) on January 27 through February 5, 1999, our Investigator collected information that revealed serious regulatory problems involving imaging tables which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), imaging tables are considered to be medical devices. The law requires that manufacturers of medical devices conform with the requirements of the Quality System Regulation (QSR) as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the requirements of the Quality System Regulation as follows:

Failure to ensure that finished devices meet all specifications prior to distribution. For example, the shipment of two model # 4133-1 imaging tables (SN2958 and SN2965) before final product release resulted in the shipment of the finished devices without final approved and tested modifications.

Failure to adequately ensure that the use of nonconforming products are closely monitored and does not become accepted practice. Your firm has been recording the use, with concession, of incoming non-conforming components on engineering change notices (ECNs) but there is no documentation justifying the use of these products. Your firm does not monitor and trend the use of nonconforming products. In addition, your firm's written procedure for "Nonconforming Product Review and Disposition" does not address whether the justifications for concessions to use non-conforming product is based on scientific evidence which your firm should be prepared to provide upon request.

Failure to maintain adequate recordkeeping procedures. For example, there was no documentation (in the device history records) of the retrofits that were done to the beta test model # 4133-1 tables and the model # 4133-1 tables that were released for sale prior to the final approval date of September 28, 1998.

Failure to establish and maintain procedures for the identification, documentation, and validation or where appropriate verification, review, and approval of design changes before their implementation. For example, changes to the product design for table models #4080 and #4100-1 series were not documented during the time frame of September 1, 1998 through October 7, 1998. Review and approval of design changes made to the tables were not recorded and the corresponding bill of materials for these changes was not updated in the computer system.

In addition, there is no design change procedure, which identifies when and how design changes will be reviewed and approved before implementation. Validation and/or verification, which may result from design changes, are not addressed.

Failure to establish and maintain adequate procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. For example, the "New Product Design Control and review, QSP 04.1.1 procedure does not clearly define design requirements, nor does it address what factors will cause inputs to be updated. Also, the following relevant aspects are not addressed: intended use, risk analysis, and design history files.

Failure to establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities and failure to document such training.

The Center for Devices and Radiological Health (CDRH), Office of Compliance, Division of Enforcement I, Diagnostic Devices Branch has reviewed the January/February 1999 Establishment Inspection Report of your firm, and the Form FDA 483 dated February 5, 1999 that was issued to you at the close of the FDA inspection. They also reviewed your product catalog. Based on their review your firm is in violation of Section 538 of Subchapter C-Electronic Product Radiation Control (EPRC) of Chapter V of the Act. [Formerly the Radiation Control for Health and Safety Act (RCHSA) of 1968] Under separate cover, the CDRH will contact you directly to address the EPRC violations.

We acknowledge that you have submitted to this office a response concerning our investigators observations noted on the Form FDA 483 dated February 5, 1999. We reviewed you response and have concluded that it is not adequate to correct all of the FDA 483 items. In your response to the issue regarding identifying training needs to ensure that all personnel are trained appropriately, you stated that a procedure has been written and is being reviewed. However, you stated that you could not promise a target date for corrective action. Likewise, you could not promise a target date for correcting the Form FDA 483 items concerning design control.

In addition, your response to the Form FDA 483 item concerning the use of nonconforming product was not adequate in that the scientific basis for making concessions to use non-conforming product was not addressed. Although you stated that your firm will incorporate the monitoring and trending of the use of non-conforming product into your procedure, you did not state how this information will be utilized to ensure that concessions to use non-conforming product does not become a common practice. The release of non-conforming products has resulted in a recall of finished devices manufactured by your firm. Your letters of response dated February 18, 1999 and February 25, 1999 will be made a permanent part of the Establishment Inspection Report of your firm.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the FDA inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by The Food and Drug Administration without further notice. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

In order to facilitate FDA in making the determination that QSR corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume export clearance for products manufactured at your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that it has conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device QSR regulation (21 CFR, Part 820). You should also submit a copy of the consultant's report, and certification by your firm's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report.

The attached guidance may be helpful in selecting an appropriate consultant. The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates: August 23, 1999, August 23, 2000, and August 23, 2001.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Road, Cincinnati, Ohio 45237.

Sincerely,

Henry L. Fielden
District Director
Cincinnati District

Enclosure